

**REMARKS**

Initially, Applicant would like to thank the Examiner for the courtesy extended during the telephone interview conducted on October 1, 2004, during which the foregoing Amendments and Remarks were discussed.

Claims 20-44 are now pending in the application. Claims 1-19 have been cancelled without prejudice to re-file. Claim 20 has been amended to: i) remove the previously recited feature that the first and second fill openings extend from the common side edge of the respective first and second film envelopes to the respective first and second interior volumes; ii) recite that the self-shaping dispersion is an uncured dispersion; and iii) recite a curing step. Support for this amendment can be found generally in the specification and claims as originally filed and specifically, in part, in lines 1-2 on page 7 of the specification. Claim 21 has been amended to recite features of the curing step of Claim 20. Claim 25 has been amended to recite a curable elastic material precursor comprising a silicone gel and a plurality of microspheres. New Claims 27-44 have been added to recite additional features of the claimed process. No new matter has been added by these Amendments. Therefore, Applicants respectfully request that examination continue on the claims as presented herein.

**Rejections under 35 U.S.C. §102**

The Office Action has rejected previous Claims 20-26 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,902,335 to Snyder, Jr. (hereinafter "Snyder"). However, it is well established that in order for a reference to be a novelty defeating reference under 35 U.S.C. §102(b), the reference must disclose each and every feature of the claimed invention. For the reasons set forth below, Applicant respectfully asserts that this standard has not been met by the disclosure of Snyder.

Amended Claim 20 and new independent Claims 34, 39 and 40 each recite, in part, a process for the manufacture of a two-layer breast prosthesis comprising a cured elastic material layer and an uncured self-shaping layer. Therefore, to be a novelty defeating reference, Snyder

must at least disclose a process for manufacturing a two-layer breast prosthesis having the combined features of a first cured elastic material layer and a second uncured self shaping layer. Snyder does not disclose these combined features.

Snyder discloses a breast prosthesis having an outer chamber 16 and an inner chamber 18. Snyder further discloses that both chambers 16 and 18 of the prosthesis are filled with a silicone gel (*see e.g.*, col. 3, ll. 18-20 and 37-41). Moreover, the silicone gel in both chambers is a silicone gel that participates in a cross-linking reaction and is thereby cured (*see e.g.*, col. 4, ll. 32-44). Therefore, Snyder fails to disclose the manufacture of a two-layer breast prosthesis having any **uncured layers**, much less an uncured layer comprised of a self-shaping dispersion. As such, Snyder does not anticipate the invention recited in Claims 20, 34, 39, 40 and those claims depending therefrom.

Furthermore, although not specifically addressed in the current Office Action, Applicant submits the following arguments in traverse of any potential rejection of the instant claims under 35 U.S.C. §103 as allegedly being obvious in view of the teachings of Snyder.

It is well settled that in order to establish a *prima facie* case of obviousness, the art of record must teach, or at least suggest, the claimed invention as a whole. Moreover, there must be adequate motivation and a reasonable expectation of success to undertake the modifications proposed in the rejection. Once again, neither standard is satisfied by the teachings of Snyder.

As noted above, the process recited in each of Claims 20, 34, 39 and 40 provides a two-layer breast prosthesis comprising, in part, an uncured self-shaping layer. In contrast, Snyder only discloses a process that provides a breast prosthesis comprised of a cured silicone gel layer. As such, Snyder is absent of any motivation, suggestion, or teaching to arrive at a breast prosthesis comprising anything other than cured silicone layers, much less an uncured layer comprised of a self-shaping dispersion. In fact, such a teaching would actually discourage the person of ordinary skill in the art from manufacturing a two-layer breast prosthesis having an uncured self shaping dispersion layer. Accordingly, Snyder does not teach or even suggest the claimed invention as a whole and similarly fails to contain any motivation or suggestion for one

of ordinary skill in the art to arrive at a breast prosthesis having an uncured layer. As such, Snyder fails to obviate the process recited in Claims 20, 34, 39 and 40 and those claims depending therefrom.

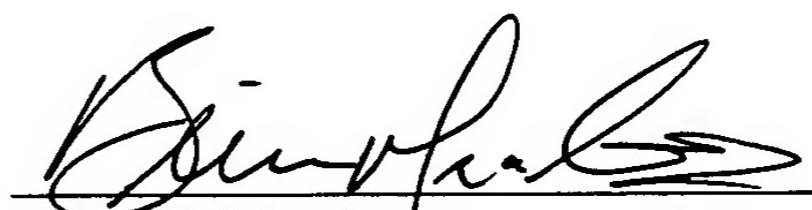
**CONCLUSION**

In light of the foregoing Amendments and Remarks, the application is believed to be in condition for allowance; accordingly, Applicants respectfully seek notification of same.

Enclosed is a credit card payment authorization form in the amount of \$1220.00, which includes the requisite RCE fee of \$790.00 and the requisite fee of \$430.00 for the two-month extension of time. No additional fee is believed due; however, the Commissioner is hereby authorized to charge any additional fees, which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

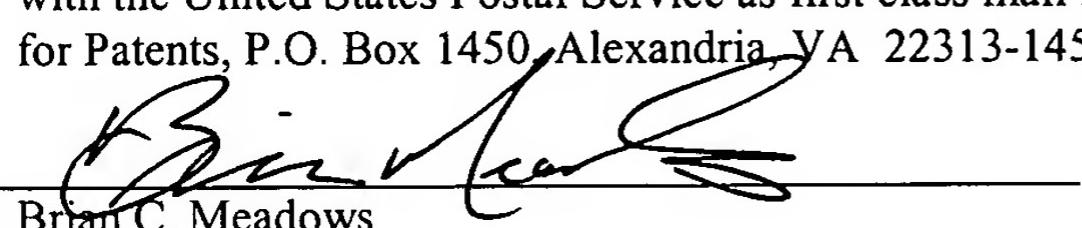


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CERTIFICATE OF MAILING

I hereby certify that this document and any documents referenced herein as being enclosed herein is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.



Brian C. Meadows

10.28.2004  
Date